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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY'S REFERENCE NO.	CONFIRMATION NO.
09 220,275	12/23/1998	STEPHEN H. FRIEND	9301-1000000	3713

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EXAMINER

MARSCHIEL, ARDIN H

ARTICLE PAPER NUMBER

DATE MAILED: 02/24/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/220,275

Applicant(s)

Friend et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 18, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 58-64 and 70-76 is/are pending in the application.
- ~~4a) ☐ Of RE-ENTRY, Claim(s) 1-57 and 65-69 have been canceled. is/are withdrawn from consideration~~
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-64 and 70-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 30, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other: \_\_\_\_\_

Applicants' arguments, filed 10/18/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to methods to enhance detection and classification of expression patterns. In contrast, the actual claims lack any expression pattern limitations, as well as lack any detection or classification limitations per se. Rather the claimed methods are directed to methods for artifact removal from biological profiles in response to a perturbation of a living cell or organism.

#### ABSTRACT

The Abstract of the Disclosure is objected to because it is too long, due to exceeding 150 words. An amended abstract is required which is submitted on its own separate sheet of paper as a single paragraph. Correction is required. See M.P.E.P. § 608.01(b).

## VAGUENESS AND INDEFINITENESS

Claims 58-64 and 70-76 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reconsideration of the instant claims reveals that antecedent basis is unclear for a significant limitation in the claims. In claim 58, line 6, the phrase "deviation of one or more experimental variables from desired values" lacks clear antecedent basis as to what "desired values" are meant. It is acknowledged that the method of claim 58 is directed to removing one or more artifacts from a measured biological response profile. Apparently, it may be thus assumed that the experimental variables are being corrected in the claimed method to remove artifactual patterns therein to produce a measured biological response profile which correctly and accurately is a response only to a perturbation as stated in the first 4 lines of claim 58, rather than containing one of more artifacts. Such a correct and accurate response is apparently what is meant by the "desired values" in line 6 of claim 58. It is, however, noted that nowhere in claim 58 is there the clear statement that "desired values" is meant to be a correct and accurate, or artifact free, biological response profile to a perturbation. Someone wishing to interpret claim 58 must rely on an assumption

in order to define what is meant by "desired values". The need for an assumption for claim interpretation supports this rejection in that the claim interpretation is vague and indefinite rather than clear and concise as required by 35 U.S.C. § 112, second paragraph, as to what antecedent basis in the method controls the metes and bounds of "desired values". Independent claims 71 and 72 also contain this "desired values" phrase without clear antecedent basis. Claims which are dependent from independent claims 58, 71, or 72 also contain this unclarity due to their dependence.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 58-61 and 71-73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Felder et al. (P/N 6,232,066) alone; or, alternatively, taken in view of Singer et al. (P/N 5,866,331).

This rejection is reiterated and maintained from the previous office action, mailed 4/19/02. Applicants argue that the claim amendments distinguish the instantly claimed methods over the reference or references applied as summarized above. This argument is centered in the concept that the instant claims remove artifacts by measurements of changes in cellular constituents resulting from deviation from experimental variables from desired values. In response the measurements of changes in the instant claims are reasonably interpreted to include measurements which are changed compared to measurements made during a perturbation as being responded to in the claims. Background corrections as in the references, or control corrections, are the result of measurements of changes in experimental variables from two standpoints. One is that these changes are measured versus the absence of a measurement or, alternatively, values of zero for the experimental variables. A second evaluation is that control or background measurements are the result of changed conditions, that is, the lack of a perturbation to the living cell or organism being measured. It is noted additionally that background or control measurements are, in fact, measurements of variable values which are changed

from experimental values due to the lack of a perturbation. An extremely common experimental procedure is to perform a control experiment with measurements thereof, side by side, with the experimental setup which would include a perturbation.

Differences in measurements reasonably are changed values between the two side by side determinations. In summary, the changes limitations in the claims are reasonably interpreted as inclusive of changes in perturbation between none versus with a perturbation. Thus, the background or control experiment changes of the references are still deemed to support practices as instantly claimed.

#### INFORMALITIES

The disclosure is objected to because of the following informalities:

It is noted that Figures 4A, 4B, 4C, and 4D are present in the formal figure set of the instant application. Confusingly, there is no Brief Description of Figures 4C or 4D, as required, in the section in the specification entitled "BRIEF DESCRIPTION OF THE DRAWINGS" starting on page 7.

It is also noted that Figures 8A, 8B, 8C, 8D, and 8E are present in the formal figure set of the instant application, but that there is no separate Brief Description of any of these different Figures in the specification on page 7 in the section entitled "BRIEF DESCRIPTION OF THE DRAWINGS".

Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2003

*Ardin Marschel*  
Legal Instrument Examiner